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ORIGINAL ARTICLE

Assessment of the renal collecting system using a pocket-sized ultrasound device

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Abstract

Purpose To assess the performance of a pocket-sized ultrasound device (PUD) for evaluating dilatation of the renal collecting system with high-end ultrasound devices (HUDs) as a reference standard.

Methods One sonographer examined both kidneys using a PUD to evaluate dilatation of the collecting system. The grading of the dilatation ranged from 0 to 4. Immediately after the examination, another sonographer blinded to the previous results performed a formal examination with a HUD.

Results Two hundred kidneys in 100 patients were included in the analysis. The agreement of grades between the PUD and HUDs was excellent (weighted kappa = 0.83; $P < 0.001$). When hydronephrosis was defined as grade 1 or higher, the test characteristics of the PUD were as follows: sensitivity 91% (95% confidence interval (CI) 79–97%), positive predictive value 73% (95% CI 60–83%), and negative predictive value 96% (95% CI 92–99%). When hydronephrosis was defined as grade 2 or higher, the test characteristics were as follows: sensitivity 88% (95% CI 73–97%), positive predictive value 75% (95% CI 59–87%), and negative predictive value 98% (95% CI 94–99%).

Conclusion Ultrasound using a PUD is useful for evaluating dilatation of the collecting system, especially for ruling out its presence.

Keywords Pocket-sized · Ultrasound · Renal collecting system · Hydronephrosis

Introduction

Several types of pocket-sized ultrasound devices (PUDs) have been developed in recent years. While PUDs cannot be substitutes for high-end ultrasound devices (HUDs), PUDs have the potential to be used for point-of-care owing to their portability. For example, these devices have allowed ultrasound examinations to be performed as an extension of the physical examination at the bedside [1]. In recent years, an increasing number of papers on the utility of these devices have been published, especially in the field of cardiology [2]; however, there are currently few data demonstrating the utility of PUDs in the renal system [3].

If PUDs correctly show the presence and degree of the dilated renal collecting system or hydronephrosis, we can manage common urinary tract diseases such as renal colic and urosepsis quickly and appropriately at the bedside inside and outside medical facilities.

The aim of this study was to assess the performance of a PUD for evaluating dilatation of the collecting system with HUDs as a reference standard in a laboratory setting.

Materials and methods

A prospective, blinded, interventional study was conducted at the ultrasound laboratory of Saiseikai Utsunomiya Hospital, a 644-bed regional general hospital in Tochigi, Japan, between May 2016 and April 2017. Transabdominal ultrasound examinations including the urinary system are performed over 11,000 times each year in this laboratory.

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The patients in this cohort were recruited using convenience sampling. They were at least 20 years old and were referred urgently from the urology outpatient clinic. The eligibility criteria were suspected ureterolithiasis, complaints including pain or discomfort in the abdomen or back, or hematuria. Patients who had a history of urological surgery and had participated in this study before were excluded.

Study protocol

Before carrying out ultrasound examinations, the investigators checked the details of the referral from the clinic and asked patients to confirm whether or not they met the criteria. After informed consent was obtained, the patient underwent an examination with a PUD and a HUD. Eleven sonographers who had at least 2 years of experience with abdominal ultrasound in the laboratory participated in this study. First, 1 of 11 sonographers examined both kidneys using a PUD with a 1.7–3.8-MHz phased-arrayed probe (Vscan version 1.2; GE Vingmed Ultrasound AS, Horten, Norway) to evaluate dilatation of the collecting system. The grading of the dilatation was defined as 0–4 and is shown in Table 1. This definition has been adopted for daily ultrasound examinations in the laboratory [4]. Color Doppler mode was not applied to differentiate the collecting system from the renal vessels. The bladder volume was not estimated.

Immediately after completion of the examination with the PUD, another sonographer blinded to the previous results performed a formal examination of the urinary tract with 1 of 4 HUDs (SSA-680A, SSA-780A, SSA-790A, Aplio 500; Toshiba Medical Systems, Tochigi, Japan) with a 3.5-MHz ± 20% convex probe. The sonographer assessed dilatation of the collecting system based on the same grading scale. Color Doppler mode was used to differentiate the collecting system from the renal vessels when necessary. If it was difficult to distinguish the dilated collecting system from parapelvic cysts with the HUD, the patient was excluded from the analysis. Each sonographer independently graded their findings without knowledge of each other's results.

Table 1 Grading of dilatation of renal collecting system

Grade	Sonographic findings
0	No detectable dilatation of the renal collecting system
1	Renal pelvis splitting without caliceal dilatation
2	Mild dilatation of the renal pelvis and calices
3	Dilatation of the renal collecting system that occupies the central echogenic renal sinus
4	Severe dilatation of the renal collecting system that is associated with cortical thinning

The renal collecting system includes the renal pelvis and calices

Data analyses

The agreement of the grade between the PUD and HUDs was analyzed on a per-kidney basis using a weighted kappa value for multiple categories. A value of 0–0.20 was considered poor, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 substantial, and 0.81–1.00 excellent [5]. If the grade of the PUD was two to four grades higher than that of the HUDs, the investigators analyzed the cause based on both images and reports.

The diagnostic accuracy of the PUD for detecting hydronephrosis was evaluated with the HUDs as a reference standard based on two criteria of hydronephrosis. One was grade 1 or higher, and the other was grade 2 or higher. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated using a 2×2 table. The 95% confidence intervals (CIs) were calculated on a binominal distribution. Statistical analyses were carried out using the STATA version 13.0 software program (StataCorp LP, College Station, TX, USA).

Results

Of the 101 patients evaluated with both the PUD and HUDs, one was excluded from the analysis because it was difficult to distinguish the dilated collecting system from parapelvic cysts with the HUD. Therefore, 200 kidneys in 100 patients (58 males and 42 females) were ultimately included in the analysis. The mean age was 56.0 ± 15.2 years (range 23–87 years), and the mean body mass index was 23.6 ± 4.1 kg/m^2 (range 15.6–32.5 kg/m^2). Table 2 shows

Table 2 Number of examinations performed with the PUD and HUD by each sonographer

Sonographer	PUD	HUD	Total
1	11	9	20
2	10	11	21
3	10	11	21
4	10	10	20
5	10	9	19
6	10	9	19
7	9	11	20
8	9	8	17
9	8	9	17
10	8	8	16
11	5	5	10
	100	100	200

PUD pocket-sized ultrasound device, *HUD* high-end ultrasound device

the number of examinations with the PUD and HUDs performed by each sonographer. Figure 1 shows typical images of grade 0–4 obtained with the PUD. The numbers of each grade given with the PUD and HUDs are shown in Table 3. The agreement of grades between the PUD and HUDs was excellent (weighted kappa = 0.83; $P < 0.001$; SE 0.069). The grade with the PUD was two to four degrees higher than that with HUDs in five kidneys, all of which were grade 2 with the PUD and grade 0 with HUDs (Table 3). In these five kidneys, sonographers misinterpreted parapelvic cysts ($n = 2$), an extrarenal pelvis ($n = 1$), renal vessels ($n = 1$), and a nonspecific hypoechoic region in the central echogenic renal sinus ($n = 1$) as dilatation of the collecting system.

When hydronephrosis was defined as grade 1 or higher, the test characteristics of the pocket-sized ultrasound device were as follows: sensitivity 91% (95% CI 79–97%), specificity 88% (95% CI 81–93%), PPV 73% (95% CI 60–83%), and NPV 96% (95% CI 92–99%). When hydronephrosis was defined as grade 2 or higher, the test characteristics were as follows: sensitivity 88% (95% CI 73–97%), specificity 94% (95% CI 89–97%), PPV 75% (95% CI 59–87%), and NPV 98% (95% CI 94–99%).

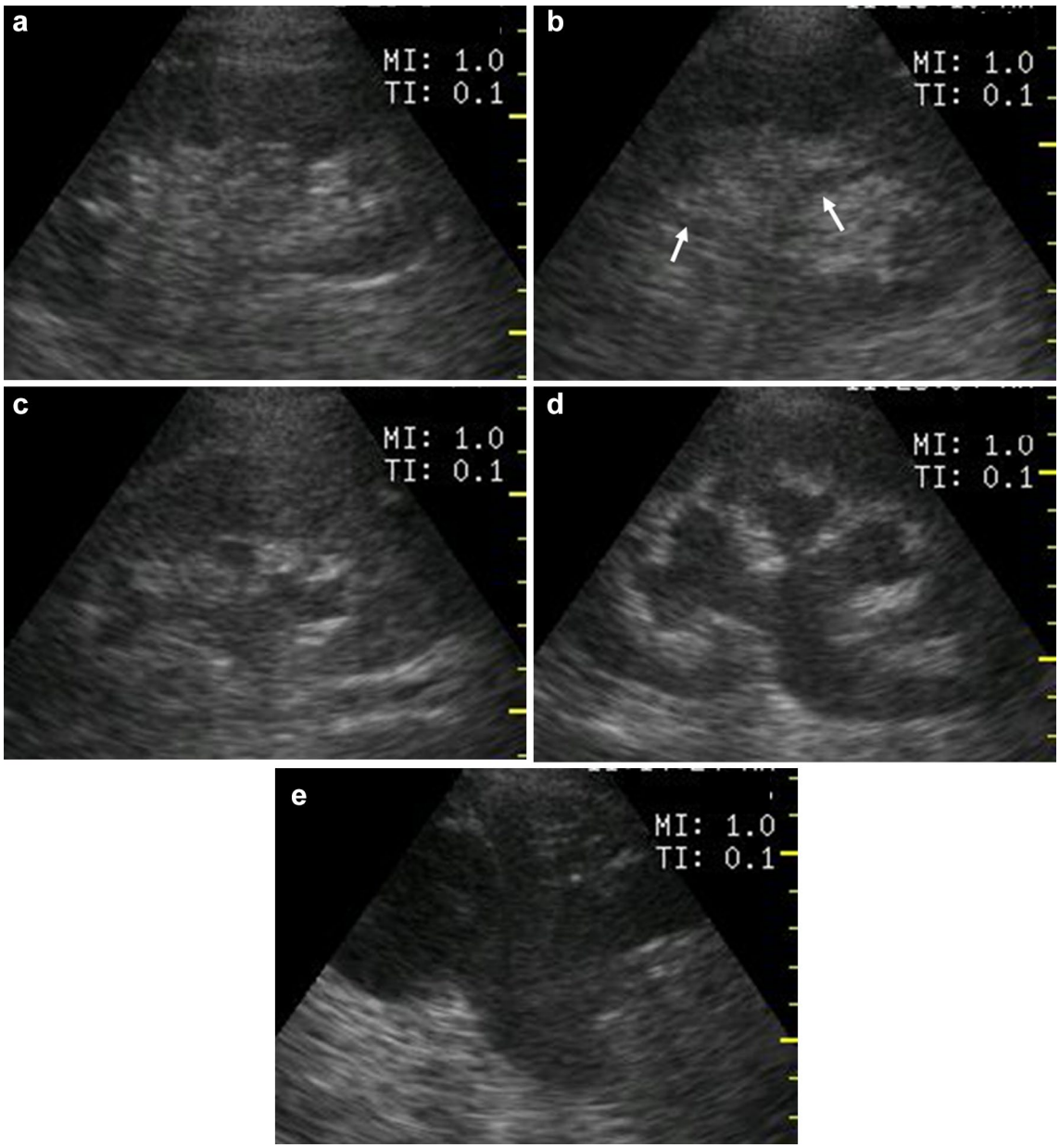

Fig. 1 Images of grades 0–4 obtained with the PUD that agreed with the grade determined with a HUD. **a** Grade 0, **b** grade 1, arrow indicates renal pelvis splitting, **c** grade 2, **d** grade 3, **e** grade 4

Table 3 Numbers of each grade given with the PUD and HUDs

PUD	HUD					
	0	1	2	3	4	Total
0	129	4	1	0	0	134
1	13	10	3	0	0	26
2	5	5	18	0	0	28
3	0	0	7	3	0	10
4	0	0	0	1	1	2
Total	147	19	29	4	1	200

PUD pocket-sized ultrasound device, *HUD* high-end ultrasound device

Discussion

Multiple grading systems have been suggested for evaluating dilatation of the renal collecting system. In antenatal and postnatal evaluations, the Society for Fetal Urology grading system has become the most commonly employed, and the urinary tract dilatation classification system proposed in 2014 is promising [6, 7]. However, no universal grading system was used in the assessment of older generations.

In the present study, we used a five-grade system (grades 0–4) because each sonographer in our laboratory was used to it [4]. This system also seemed to be suitable for assessing the performance of the PUD for several reasons. Renal pelvis splitting without caliceal dilatation, which was defined as grade 1 in this study, is classified as normal in other grading systems [8, 9]. However, our previous study showed that 18% of patients with ureterolithiasis had renal pelvis splitting without caliceal dilatation in the kidney on the symptomatic side [4]. The definition of grade 3, which was based on the degree of dilatation of the renal collecting system in the central echogenic renal sinus, was found to be simple to use when evaluating the degree using the PUD.

The agreement of the grade between the PUD and HUDs was excellent based on the weighted kappa value for multiple categories. Disagreement regarding the grade occurred in 31 of 200 kidneys (15.5%). We may reasonably conclude that the disagreement between the PUD and HUDs was caused by not only differences in the performance of these devices but also inter-observer reliability of the grading system. We also assumed that the investigators could identify the causes for discrepancies due to differences in the performance of these devices if the grade with the PUD was two to four degrees higher than that with the HUDs. In these cases, parapelvic cysts, an extrarenal pelvis, renal vessels, and a nonspecific hypoechoic region in the central echogenic renal sinus were misinterpreted as dilatation of the intrarenal collecting system with the PUD. We must bear in mind that these findings can be misinterpreted as hydronephrosis with a PUD. If color flow mode in the PUD had been applied to differentiate the collecting system from the renal vessels, the rate of disagreement might have been lower.

In the present study, we set two evaluation criteria for hydronephrosis to assess the diagnostic accuracy of the PUD: grade 1 or higher and grade 2 or higher. As mentioned before, some grading systems do not include renal pelvis splitting without caliceal dilatation in hydronephrosis [8, 9]. Both criteria showed similar results with HUDs as a reference standard. The PPV with grade 1 or higher and grade 2 or higher was 73 and 75%, while the NPV was 96 and 98%, respectively. These results indicate that a PUD used by skilled sonographers is useful for ruling out hydronephrosis, although the findings should be reevaluated with a HUD when the PUD detects positive findings.

This prospective blinded study has several limitations. First, the convenience sample was based on the availability of the study investigators. The investigators included as many patients as possible to reduce the selection bias when they had time to perform the study. Second, this study was performed in an ultrasound laboratory. The patients were selected and referred from the urology outpatient clinic. Ultrasound with the PUD was performed by skilled sonographers. For these reasons, it is uncertain whether these results can be directly applied to point-of-care ultrasound performed by clinicians or other healthcare providers at the bedside. Nevertheless, this study revealed that the PUD itself was useful for evaluating dilatation of the collecting system. Third, we evaluated the utility of a single type of PUD, without using the color Doppler mode, which was included in the device. Other types of PUD with or without color Doppler modes should be assessed for generalization.

Conclusion

Ultrasound using a PUD by skilled sonographers is considered to be useful for evaluating dilatation of the collecting system, especially for ruling out its presence. Such validation needs to be extended to clinician-performed ultrasound at the bedside.

Compliance with ethical standards

Ethical statements This study was approved by the Ethics Committee of Saiseikai Utsunomiya Hospital, and written informed consent was obtained from all patients.

Conflict of interest Toru Kameda has received a lecturer honorarium from GE Healthcare unrelated to the submitted work. Kumiko Uebayashi, Kazuko Wagai, Fukiko Kawai, and Nobuyuki Taniguchi declare that they have no conflicts of interest.

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